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K012115

Serim™ RESEARCH CORP

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# 510(k) SUMMARY

**Serim™ Blood Leak Test Strips-2**

**Submitted by:**

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Contact person: Robert J. Carrico

Date prepared: July 5, 2001

**Device Name:**

Trade name: SERIM™ Blood Leak Test Strips-2
Common name: Occult blood test strip

Classification name: Dialysis Blood Leak Test Strip

**Legally Marketed Equivalent Device:**

This product is similar in design, composition and function to the occult blood test pad on Chemstrip 10 urine test strip manufactured by Boehringer Mannheim Corporation which was the subject of Premarket Notification K896454 The product is similar in utility to the cyanomethemoglobin assay. Supportive data for substantial equivalence to the latter was obtained.

**Description of the SERIM Blood Leak Test Strip-2**

The SERIM Blood Leak Test Strips-2 consist of a 0.2 x 0.2 inch reagent pad attached to one end of a white 0.2 x 3.25 inch polystyrene handle. The reagent pad is immersed into a sample, removed immediately and allowed to react for 60 seconds. Then the reagent pad color is compared to two color blocks on the bottle label. One color block marked Negative is yellow with a few green speckles. If a reagent pad has a similar yellow color the dialysate does not contain significant blood. The second color block is green with small yellow speckles and is marked Positive. A reagent pad with green color equal to or darker than this color block indicates the presence of a significant blood leak.

The Association for the Advancement of Medical Instrumentation(AAMI) standards recommends that blood loss be limited to 0.35 mL/minute or less. This calculates to 5.5 mg/dL hemoglobin at 25% hematocrit. (AAMI Standards and Recommended Practices, Vol. 3, 1998, p. 57) SERIM Blood Leak Test Strips-2 are designed to give a positive readings with 1.5 mg/dL hemoglobin in acid/bicarbonate buffer, pH 7.4. Thus, a positive test strip reading corresponds to approximately 0.1 mL/minute blood loss.

Serim Blood Leak Test Strips-2 are similar in function to Serim Blood Leak Test Strips-1, premarket notification no. K990206, currently being marketed to dialysis clinics. The formulation in Serim Blood Leak Test Strips-2 was changed for proprietary reasons. A major change was the replacement of the oxidant diisopropylbenzene dihydroperoxide in Serim Blood Leak Test Strips-1 with 2,5-dimethylhexane-2,5-dihydroperoxide in Serim Blood Leak Test Strips-2.

**Intended Use:**

Hemodialyzers are equipped with photometric sensors in the dialysate stream to detect blood leaks at the dialysis membranes. The sensors measure red color in the dialysate due to hemoglobin in red blood cells. Sensors are calibrated to sound an alarm when blood loss reaches 0.35 mL/minute.

A confirmed blood leak requires termination of the dialysis session and restarting with a new dialyzer. Occasionally false alarms occur possibly due to gas bubbles in the sensor. Since interrupting a dialysis session is stressful for the patient, technicians prefer to confirm an alarm before taking further steps. SERIM Blood Leak Test Strips-2 provide a quick and convenient means to test for occult blood in hemodialysis fluids.

**Technological Comparison to Predicate Device:**

SERIM Blood Leak Test Strips-2 and Chemstrip occult blood test strips both utilize the peroxidase-like activity of hemoglobin to detect whole blood in fluids. Both tests have an organic peroxide and a chromogen dried in test pads. When the pads are exposed to test samples the organic peroxide and chromogen react extremely slowly unless hemoglobin from red blood cells is present. Hemoglobin catalyzes the oxidation of the chromogen to produce green color. The rate of color formation is dependent on the concentration of hemoglobin in the test sample. In some

applications the level of occult blood in samples is estimated from the amount of color produced. However, a positive/negative answer is preferable in the hemodialysis application. SERIM Blood Leak Test Strips-2 have adequate sensitivity to detect hemoglobin at the required levels as discussed above. Two color blocks used in the test provide a clear distinction between Positive and Negative readings. If a reading between the two blocks is obtained a very small leak may be present and dialysis can be continued because the leak can seal.

**Statement of Substantial Equivalence**

SERIM Blood Leak Test Strips-2 from three production lots were used to test blood standards in blind studies. Sixty negative strip readings (100% specificity) were obtained with dialysis buffer without blood. Chemstrip test strips for occult blood also gave negative readings for these samples. Sixty positive strip readings (100% sensitivity) were obtained with dialysis buffer containing non-hemolyzed blood at 1.5 mg/dL hemoglobin, determined by the cyanmethemoglobin method. Chemstrip test strips for occult blood gave readings equal to or greater than 250 erythrocytes/uL for all of the samples with 1.5 mg/dL hemoglobin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 3 0 2001

Ms. Patricia Rupchock
Manager of Regulatory Affairs
Serim™ Research Corporation
P.O. Box 4002
ELKHART IN 46514-0002

Re: K012115
Trade/Device Name: Serim™ Blood Leak Test Strips - 2
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 FJD
Dated: October 4, 2001
Received: October 9, 2001

Dear Ms. Rupchock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012115

Device Name: Serim Blood Leak Test Strip - 2

## Indications For Use:

Serim Blood Leak Test Strips – 2 provide a rapid and convenient means for testing dialysate for blood if a dialyzer membrane leak is suspected during the conventional hemodialysis procedure or continuous renal replacement therapy procedures such as continuous arteriovenous hemodialysis or continuous venovenous hemodialysis.

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use (Optional Format 1-2-96)

Nancy C Brogdon

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K012115